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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,159	10/02/2000	Keting Chu	1581.002/200130.494	4111

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/678159	CHU	
	Examiner	Art Unit	
	GAMBEL	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 5/17/02

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration. 1-9, 22

5)☑ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 10-21, 23

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

1. Applicant's election without traverse of Group IV, drawn to methods of treating autoimmune diseases with CD40-specific antibodies and the species psoriasis (claims 10-21 and 23) in Paper No. 10 is acknowledged.

Claims 1-9 and 22 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species.

Claims 10-21 and 23 are under consideration in the instant application.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

3. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Applicant should amend the page 12, lines 23 of the instant specification to delete the underlining.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the 5H7 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

6. Claim 16 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is indefinite in the recitation of "5H7" because its characteristics are not known. The use of "5H7" antibody as the sole means of identifying the claimed antibody renders the claim indefinite because "5H7" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation s to define completely distinct antibodies or cell lines.

The applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined *under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 10-14,18-21 and 23 are rejected under 35 U.S.C. § 102(e) as being anticipated by Aruffo et al. (U.S. Patent No. 6,051,228) (1449) (see entire document).

Aruffo et al. teach methods of inhibiting disease states, including autoimmune diseases such as psoriasis (e.g. column 21, paragraph 3) with CD40-specific antibodies which block CD40:CD40L interactions, including monoclonal, chimeric and humanized antibodies (e.g. Detailed Description of the Invention), including wherein the antibodies are administered parenterally in amounts sufficient to arrest the disease or its complications (e.g. columns 21-22). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat autoimmune diseases such as psoriasis with CD40-specific antibodies.

10. Claims 10-14, 18-21 and 23 are rejected under 35 U.S.C. § 102(e) as being anticipated by Yellin et al. (U.S. Patent No. 6,340,459) (see entire document).

Yellin et al. teach methods of inhibiting disease states, including autoimmune diseases such as psoriasis (e.g. columns 12-15, including column 13, paragraph 3 and column 14, paragraph 7) with CD40-specific antibodies which block CD40:CD40L interactions and activation, including monoclonal, chimeric and humanized antibodies (e.g. Detailed Description of the Invention; including column 6, paragraphs 3, 6 and 8; column 7, paragraph 1; columns 12-15), including wherein the antibodies are administered parenterally in amounts sufficient to inhibit an inflammatory response (e.g. columns 12-13). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat autoimmune diseases such as psoriasis with CD40-specific antibodies.

11. Claims 10-21 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Aruffo et al. (U.S. Patent No. 6,051,228) AND/OR Yellin et al. (U.S. Patent No. 6,340,459) in view of de Boer et al. (U.S. Patent No. 5,397,703) and the art recognized use of monoclonal, human monoclonal and recombinant antibodies, as acknowledged on page 8, paragraph 2 to page 12, paragraph 1 of the instant specification.

Aruffo et al. teach methods of inhibiting disease states, including autoimmune diseases such as psoriasis (e.g. column 21, paragraph 3) with CD40-specific antibodies which block CD40:CD40L interactions, including monoclonal, chimeric and humanized antibodies (e.g. Detailed Description of the Invention), including wherein the antibodies are administered parenterally in amounts sufficient to arrest the disease or its complications (e.g. columns 21-22). See entire document

Yellin et al. teach methods of inhibiting disease states, including autoimmune diseases such as psoriasis (e.g. columns 12-15, including column 13, paragraph 3 and column 14, paragraph 7) with CD40-specific antibodies which block CD40:CD40L interactions and activation, including monoclonal, chimeric and humanized antibodies (e.g. Detailed Description of the Invention; including column 6, paragraphs 3, 6 and 8; column 7, paragraph 1; columns 12-15), including wherein the antibodies are administered parenterally in amounts sufficient to inhibit an inflammatory response (e.g. columns 12-13). See entire document.

Aruffo et al. and Yellin et al. differ from the claimed methods by not disclosing the particular 5H7 CD40-specific antibody recited in claim 16.

De Boer et al. teach the advantages of generating antibodies to cell surface antigens using immunogen recombinant insect cells (see entire document, including Background of the Invention, Summary of the Invention and Detailed description of the invention, including Columns 9-10), including the CD40-specific antibody 5H7 (column 17, Table 2).

Given the binding and specificity properties of the CD40-specific 5H7 antibody taught by de Boer et al., it would have been obvious to substitute the 5H7 antibody into the methods to treat psoriasis with CD40-specific antibodies as taught by Aruffo et al. and Yellin et al. Given the well known use and advantages of recombinant antibodies and antibody fragments as taught by Aruffo et al. and Yellin et al. in human therapy, one of ordinary skill in the art would have been motivated to administer the CD40-specific 5H7 antibody, including monoclonal, chimeric or humanized forms of this antibody to treat psoriasis at the time the invention was made. Page 8, paragraph 2 to page 12, paragraph 1 of the instant specification acknowledges the well use of monoclonal, human monoclonal, and recombinant antibodies and antigen-binding fragments thereof for human therapy at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Claims 10-21 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Aruffo et al. (U.S. Patent No. 6,051,228) AND/OR Yellin et al. (U.S. Patent No. 6,340,459) alone or in view of de Boer et al. (U.S. Patent No. 5,397,703) and the art recognized use of monoclonal, human monoclonal and recombinant antibodies, as acknowledged on page 8, paragraph 2 to page 12, paragraph 1 of the instant specification and further in view of Golstein et al. (U.S. Patent No. 6,274,711)

Aruffo et al. (U.S. Patent No. 6,051,228) AND/OR Yellin et al. (U.S. Patent No. 6,340,459) alone or in view of de Boer et al. (U.S. Patent No. 5,397,703) have been taught above.

Although Aruffo et al. and Yellin et al. Teach treating psoriasis with CD40-specific antibodies, including modes of administration to achieve effective amount to inhibit CD40:CD40 interactions and activation as well as to inhibit inflammatory responses associated with the disease, these primary references do not explicitly state that the administration should be intradermally for treating psoriasis.

Given the nature and the complications of psoriasis, one of ordinary skill in the art would have been motivated to treat a disease such as psoriasis intradermally with CD40-specific in order to provide an effective amount of CD40-specific antibodies to inhibit CD40:CD40 interactions and activation as well as to inhibit inflammatory responses associated with the disease, as acknowledged by Golstein et al., which teach various modes of administration depending on the nature of the condition, including intradermal administration (e.g. see column 28, paragraph 5 to column 29, paragraph 1) with immunosuppressants associated with various diseases, including psoriasis (e.g. see column 4, paragraph 2)

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

PGambel

Phillip Gambel, PhD.
Primary Examiner
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July 18, 2002